

Department of Health
Notice of Rulemaking Hearing
Tennessee Medical Laboratory Board
Division of Health Related Boards

There will be a hearing before the Tennessee Medical Laboratory Board to consider the promulgation of a new rule and amendments to rules pursuant to T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, 68-29-105, 68-29-127, and 68-29-129. The hearing will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204 and will take place in the Division of Health Related Board's Conference Room on the Third Floor of the Heritage Place Building located at 227 French Landing, Nashville, TN at 2:30 p.m. (CST) on the 19th day of December, 2006.

Any individuals with disabilities who wish to participate in these proceedings (review these filings) should contact the Department of Health, Division of Health Related Boards to discuss any auxiliary aids or services needed to facilitate such participation or review. Such initial contact may be made no less than ten (10) days prior to the scheduled meeting date (the date such party intends to review such filings), to allow time for the Division to determine how it may reasonably provide such aid or service. Initial contact may be made with the ADA Coordinator at the Division of Health Related Boards, 227 French Landing, Suite 300, Heritage Place, MetroCenter, Nashville, TN 37243, (615) 532-4397.

For a copy of the entire text of this notice of rulemaking hearing contact:

Jerry Kosten, Regulations Manager, Division of Health Related Boards, 227 French Landing, Suite 300, Heritage Place, MetroCenter, Nashville, TN 37243, (615) 532-4397.

Substance of Proposed Rules

Amendments

Rule 1200-6-1-.03 Necessity of Licensure, is amended by deleting the catchline in its entirety and substituting instead the catchline Necessity of Licensure and Licensure Exemptions, and is further amended by adding the following language as new paragraph (3):

- (3) The following personnel are exempt from the licensure requirements imposed pursuant to the "Tennessee Medical Laboratory Act":
 - (a) All personnel performing the testing described in rule 1200-3-.02 (6) in the laboratory or portion of the otherwise licensed laboratory exempted from licensure pursuant to that rule.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, and 68-29-105.

Rule 1200-6-1-.12 Continuing Education, is amended by adding the following introductory language immediately after the catchline, so that as amended, the catchline and the introductory language shall read:

1200-6-1-.12 Continuing Education. Continuing education is planned, organized learning acts acquired during licensure to maintain, improve or expand a licensee's knowledge and skills relevant to medical laboratory practice in order for the licensee to develop new knowledge and skills relevant to the practice, education or theory development to improve the safety and welfare of the public.

Authority: T.C.A. §§ 4-5-202, 4-5-204, and 68-29-105.

Rule 1200-6-1-.22 Qualifications, Responsibilities and Duties of Testing Personnel, is amended by deleting subparagraph (1) (a) in its entirety and substituting instead the following language, and is further amended by inserting the following language as subparagraph (1) (b) and renumbering the remaining subparagraphs accordingly, so that as amended the new subparagraphs (1) (a) and (1) (b) shall read:

(1) (a) To become licensed as a medical laboratory technologist an applicant must:

1. Submit satisfactory evidence of successfully completing and passing a national certifying examination and being nationally certified at the technologist level by either the ASCP, NCA, NRCC, NRM, ABB, AMT or any other national certifying agency recognized by the Board (Successful completion of the Health and Human Services proficiency examination in clinical laboratory science does not meet this criteria for licensure); and
2. In addition to possessing the national certification required by part 1. of this subparagraph, submit satisfactory evidence of having met one (1) of the following educational criteria:
 - (i) A baccalaureate degree in medical technology or in one of the biological, chemical or physical sciences, and completion of a medical laboratory technologist training program that was, at the time of graduation, either
 - (I) approved or under the auspice of the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS); or
 - (II) approved by a national accrediting agency acceptable to the Board; or

- (III) completed in a specialty program conducted by a hospital or other institution approved pursuant to Rule 1200-6-2-.04; or
 - (ii) A baccalaureate degree from an accredited college/university, completion of an accredited MLT/CLT training program and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1) (g); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (f); or
 - (iii) A baccalaureate degree from an accredited college/university, completion of an official military laboratory procedures course of at least fifty (50) weeks duration in residence and have held the military enlisted occupational specialty of Medical Laboratory Specialist, and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1) (g); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (f); or
 - (iv) A baccalaureate degree from an accredited college/university and five (5) years of full time clinical laboratory work experience as defined in subparagraph (1) (g); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (f).
- (1) (b) Those applicants for medical laboratory technologist licensure who do not possess a baccalaureate degree may be approved for licensure upon having submitted to the Board's administrative office directly from the national certifying agency satisfactory proof of having successfully completed on or before September 1, 1997 (the date on which CLIA required at a minimum an associate's degree or its equivalent for those who would be performing high complexity testing and the date on which the Board ceased providing the state licensure examination) a medical laboratory technologists national certification examination and the applicant has submitted to the Board's administrative office directly from the issuing authorities satisfactory proof that the applicant met one (1) of the following criteria:
- (i) The applicant had, on or before September 1, 1997, received a passing grade on a Health and Human Services proficiency examination in clinical laboratory science and had completed five (5) years of full time clinical laboratory work experience as defined in subparagraph (1) (g); or

- (ii) The applicant had, on or before September 1, 1997, completed a minimum of ninety (90) semester hours including science course work equivalent to that required in a laboratory science education program as defined by (1) (f) of this rule; and had, on or before September 1, 1997, completed a medical laboratory technologist training program that was approved at the time of graduation by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the Board.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, and 68-29-118.

Rule 1200-6-3-.02 Licensing Procedures is amended by deleting the catchline in its entirety and substituting instead the catchline Licensing Procedures and Licensure Exemptions, and is further amended by adding the following language as new paragraph (6):

- (6) Pursuant to T.C.A. § 68-29-104(8) the Board hereby exempts the following laboratories (or portions of otherwise licensed laboratories) and the personnel performing tests in those laboratories (or portions of otherwise licensed laboratories) from the requirements imposed pursuant to the "Tennessee Medical Laboratory Act":
 - (a) Any laboratory (or portion of an otherwise licensed laboratory) which is operated by the Tennessee Department of Health and in which the only testing on human specimens is that which is required pursuant to an investigation ordered by or in cooperation with the State Epidemiologist or law enforcement agency the results of which are reported only to the State Epidemiologist, CDC or law enforcement officials as required by federal law.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-104, and 68-29-105.

New Rule

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1200-6-1-.18 Unethical Conduct

1200-6-1-.18 Unethical Conduct.

- (1) Unethical conduct shall include, but not be limited to:
 - (a) Failing to exercise reasonable diligence to prevent partners, associates, and employees from engaging in conduct which would

violate any provisions of the Tennessee Medical Laboratory Act or any rule, regulation, or order of the Board.

- (b) Penalizing medical laboratory personnel for reporting violations of any provisions of the Tennessee Medical Laboratory Act or any rule, regulation, or order of the Board.

- (2) Violations of this rule shall subject a licensee to disciplinary action, as provided in Rule 1200-6-1-.15.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-127, and 68-29-129.

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Contact who can answer questions concerning this notice of rulemaking hearing, technical contact for disk acquisition, and person who will approve final copy for

publication: Jerry Kosten, Regulations Manager, Division of Health Related Boards, 227 French Landing, Suite 300, Heritage Place, MetroCenter, Nashville, TN 37243, (615) 532-4397.

I certify that this is an accurate and complete representation of the intent and scope of rulemaking proposed by the Tennessee Medical Laboratory Board.

Robbie H. Bell, Director
Health Related Boards

Subscribed and sworn to before me this the 12th day of October, 2006.

Notary Public

My commission expires on the 20th day of March, 2010.

The notice of rulemaking set out herein was properly filed in the Department of State on the ____ day of _____, 2006.

Riley C. Darnell
Secretary of State

By: _____